

RESPONSE

I. Status of the Claims

Prior to the Action, claims 1-19, 23, 51, 52 and 93-99 were pending and have been examined without entry of a restriction or species election. Claims 95 and 98 are allowed and claims 8, 18 and 23 are allowable (Action at summary page; page 2; and page 15).

Presently, claims 1, 9-12, 93, 94, 96 and 97 have been amended, without prejudice or disclaimer, to apply the Action's indication of allowable subject matter to all claims. Claims 100-122 have been added, which are fully supported by the original application. No claims have been cancelled. Should any small entity fees be deemed necessary for the new claims, such fees should be deducted from Peregrine Pharmaceuticals, Inc. Deposit Account No. 50-3493/4001.003000.

Claims 1-19, 23, 51, 52 and 93-122 are therefore in the case. According to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

II. Support for the Claims

Support for the revised and new claims exists throughout the specification and claims of the original and parent applications.

Claim 1 has been revised to define the claimed antibody as a "monoclonal" antibody. This was originally recited in claim 12, which provides the required support, in addition to allowed claim 98 and throughout the specification.

Claims 9-11 have each been revised to replace the succinct reference to Table 3 and/or Table 4 with the pertinent text from such tables. Table 3 and/or Table 4 in the specification thus provide the required support, in addition to throughout the specification.

Claim 12 has been revised to define the claimed antibody as "an IgM antibody". This is supported throughout the specification, *e.g.*, first at page 16, line 22.

Claims 93, 94, 96 and 97 have each been revised to define the claimed antibody as a "monoclonal" antibody, as set forth above for claim 1. Support exists in original claim 12 and allowed claim 98, in addition to throughout the specification.

New dependent claims 100, 108, 113 and 118 further define the recited antibody as binding to phosphatidylserine in combination with a protein cofactor. This is an inherent feature of the 3G4 antibody, deposited before the priority date, and is supported throughout the original and amended specification.

New dependent claims 101, 103, 109, 114 and 119 refer to the ELISA of Example IV-D in the specification (pages 243-244), and are supported thereby. Additional support also exists throughout the specification, *e.g.*, at least at page 147, lines 30-32 (solid support) and page 160, lines 31-32 (secondary antibody). The use of a blocking buffer that comprises 10% bovine serum, as in dependent claims 102, 104, 110, 115 and 120, is supported by Example IV-D, particularly at page 243, line 17.

New claims 105 and 106, in dependent and independent form respectively, recite a composition in which the antibody is the deposited 3G4 antibody, as supported by claim 1 and throughout the specification and claims as filed.

New claim 107 is an independent claim based upon allowable claim 18, and is supported thereby.

New claims 111 and 112, in dependent and independent form respectively, recite a pharmaceutical composition in which the antibody is the deposited 3G4 antibody, as supported by claims 1 and 96 and throughout the specification and claims as filed.

New claims 116 and 117, in dependent and independent form respectively, recite that the purified antibody is the deposited 3G4 antibody, as supported by claims 1 and 97 and throughout the specification and claims as filed.

New claim 121 further defines the recited hybridoma as producing the deposited 3G4 antibody, as supported by claims 1 and 98 and throughout the specification and claims as filed.

Finally, new claim 122 reflects the text of claim 1 prior to the present amendment, and is supported thereby.

It will therefore be understood that no new matter is included within any of the amended or new claims.

III. Amendments to the Specification and Interview Summary

It has come to Applicants' attention that the 3G4 antibody, which was deposited before the priority date of the present application, was placed in the incorrect category in the specification. This is now corrected by the concurrent amendments to the specification. As summarized below, the amendments have already been approved by the Office.

The 3G4 antibody is also disclosed in five co-pending applications of the present inventors (Serial Nos. 10/642,120, 10/642,060, 10/642,124, 10/642,122 and 10/642,119), which concern methods and kits for treating viral infections using antibodies that bind to an aminophospholipid, such as phosphatidylserine (PS), or anti-viral immunoconjugates thereof. These five applications have the same specification and priority date as the present case.

After undertaking examination for the five anti-viral applications, Examiner Goddard kindly agreed to grant Applicants a personal interview. Applicants very much appreciate Examiner Goddard's participation in interviews and review of documents, which has aided efficient examination and resulted in agreement on the present amendments to the specification.

In preparation for a personal interview at the Office, Applicants' representatives, Shelley Fussey and Laura Coruzzi¹, and Examiner Goddard held a first telephone interview on Friday, August 25, 2006. Applicants advised Examiner Goddard that the 3G4 antibody (deposited before the priority date) had been placed in the incorrect category in the specification and that Applicants sought to correct this by amendment. Following the August 25, 2006 telephone interview, Applicants submitted the proposed amendments via facsimile for the Examiner's review, along with two related publications on behalf of the inventors. Examiner Goddard agreed to review the submitted materials and discuss entry of the proposed amendments with others at the Office.

On Monday, August 28, 2006, Examiner Goddard telephoned Shelley Fussey and advised that, following discussions with a Supervisory Patent Examiner and a Quality Assurance Specialist, the proposed amendments to the specification were acceptable and would be entered upon formal submission. Examiner Goddard noted that the 3G4 antibody was deposited with the ATCC before the applications' priority date. The present amendments to the specification implement this agreement. An Information Disclosure Statement (IDS) listing the submitted publications from the inventors (Ran *et al.*, 2005; and Luster *et al.*, 2006) will be submitted shortly to complete the record.

On Thursday, August 31, 2006, Applicants' representatives, Shelley Fussey and Jennifer Chheda¹, and Examiner Goddard proceeded with personal interviews at the Office for the five anti-viral applications. Two issues of relevance to the claims in the present application were discussed.

¹ 'Authorization to Act in a Representative Capacity' documents were filed in the five anti-viral applications, so that Applicants' co-counsel and registered practitioners, Laura A. Coruzzi and Jennifer J. Chheda, could participate in telephone and personal interviews in the anti-viral applications.

Applicants first proposed entry of a dependent claim to match the amendments to the specification, to which the examiner agreed. Present dependent claims 100, 108, 113 and 118 each having the same text, implement this agreement.

Applicants next proposed entry of dependent claims referring to the ELISA of Example IV in the specification, particularly as described in Example IV-D. Examiner Goddard advised that particular steps of the ELISA be recited, such as blocking and detecting steps. The sets of two dependent claims, claims 101 and 102, 103 and 104, 109 and 110, 114 and 115 and 119 and 120, each having the same text, implement this agreement.

Applicants appreciate Examiner Goddard's time and the productive discussions, leading to agreement on the present amendments to the specification. In light of the guidance in the Official Action in this case, all claims are now believed to be in condition for allowance. Should Examiner Goddard have any remaining concerns, Applicants respectfully request a telephone call to the undersigned Applicants' representative in order that matters may be resolved as efficiently as possible.

IV. Claims Free From Rejection and Response Summary

Applicants appreciate the indication that most claims are free from rejection (other than provisional rejections for obviousness-type double patenting), and that several claims are allowed and allowable (Action at summary page; page 2; and page 15).

In particular, claims 2-19, 23, 51, 52, 95, 96, 98 and 99 are free from the single anticipation rejection under 35 U.S.C. § 102(b), and no claims have been rejected as legally obvious under 35 U.S.C. § 103(a). In light of this guidance from the Office, Applicants elect to place all claims in condition for allowance using the language already found to be novel and non-obvious. Accordingly, claims 1, 93, 94, 96 and 97 have each been revised to define the claimed

antibody as a "monoclonal" antibody, as in allowed claim 98 and claim 12 (free from prior art rejection), and are thus now allowed.

Allowable claim 18 has also been drafted as independent claim 107, which is also now allowed.

Claims 1-19, 23, 93-95 and 97-99 are free from rejection under 35 U.S.C. § 112, first paragraph on the basis of enablement. The enablement rejection of claims 51, 52 and 96 is overcome by Applicants' response at **Section VI**, including the solicited antibody competition data in the Thorpe declaration.

Claims 1-8, 12-19, 23, 51, 52 and 94-98 are free from rejection under 35 U.S.C. § 112, second paragraph. The clarity rejections of claims 9-11, 93 and 99 are overcome by Applicants' response at **Section V**.

The provisional obviousness-type double patenting rejections are overcome by the enclosed terminal disclaimer.

At least claims 1-19, 23, 51, 52 and 93-114 are therefore in condition for allowance, based upon the Action's indication of allowable subject matter. Claim 122 is also believed to be in condition for allowance, as detailed later in this response.

V. Rejection of Claims 9-11, 93 and 99 Under 35 U.S.C. § 112, Second Paragraph

Claims 9-11, 93 and 99 are first rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Although Applicants respectfully traverse, the rejections are overcome.

A. Substantially

Claims 9, 11, 93 and 99 are first rejected as allegedly being indefinite in regard to the term "substantially" (Action at page 2). Applicants are puzzled that the Action has questioned

the clarity of "substantially" despite extensive case law showing the propriety of the term substantially and the standard use of this term in issued U.S. patents, including those claiming antibodies.

By way of example only, in *Verve LLC vs. Crane Cams Inc.*, 65 USPQ2d 1051 (Fed. Cir. 2002), the Federal Circuit vacated a summary judgment that a patent was invalid for indefiniteness based upon the failure of the specification and prosecution history to define sufficiently the claim term "substantially". It was held that expressions like "substantially" are used to accommodate minor variations appropriate to secure an invention. Thus, the term "substantially" is not indefinite when it serves reasonably to describe the scope of the subject matter. The Federal Circuit commented further:

"Expressions such as 'substantially' are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention. Such usage may well satisfy the charge to 'particularly point out and distinctly claim' the invention, 35 U.S.C. §112, and indeed may be necessary in order to provide the inventor with the benefit of his invention. In *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819, 821-22, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988) the court explained that usages such as 'substantially equal' and 'closely approximate' may serve to describe the invention with precision appropriate to the technology and without intruding on the prior art. The court again explained in *Ecolab Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367, 60 USPQ2d 1173, 1179 (Fed. Cir. 2001) that 'like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter,' quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217, 36 USPQ2d 1225, 1229 (Fed. Cir. 1995).

Verve LLC vs. Crane Cams Inc., emphasis added.

The *Verve vs. Crane* decision is just one in a long line of cases from the Federal Circuit, its predecessor court and the Board holding that use of the term "substantially" does not render a claim indefinite. See e.g., *Andrew Corp. v. Gabriel Electronics*, 6 USPQ2d 2010 (Fed. Cir. 1988); *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 221 USPQ 568 (Fed. Cir. 1984);

In re Mattison, 184 USPQ 484 (CCPA 1975); *Ex parte Smith*, 43 USPQ 157 (PTO Bd. App. 1937).

Even where the specification does not provide some standard for measuring the degree of a relative term, terms such as substantially are still definite so long as one of ordinary skill in the art would nevertheless be reasonably apprised of the scope of the invention in view of the knowledge in the art. *Seattle Box Co.* at 574. In the present case, the specification provides standards for measuring the degree of the relative term *and* those of ordinary skill in the art would anyway understand the term.

For example, terms such as "an antibody that binds to substantially the same epitope as...", as in claims 93 and 99, routinely appear in the claims of issued U.S. patents in the biotech field and are therefore *prima facie* definite. 35 U.S.C. § 282. In addition, in further defining antibodies that bind to substantially the same epitope as 3G4, the present specification refers to a number of issued U.S. patents that disclose and claim competing antibodies defined in comparison to a reference antibody (*e.g.*, first mentioned in the specification at pages 11-12). These include U.S. Patent Nos. 6,342,219 and 6,342,221, which are specifically incorporated by reference into the specification for purposes including:

"...further supplementing the present teaching concerning how to make antibodies that bind to the same or substantially or essentially the same epitope as a given antibody, such as 3G4, or that effectively compete with a given antibody for binding to an antigen".

Specification at page 12, lines 12-15.

Of relevance to this issue, a § 112, second paragraph rejection over the term "substantially" was entered and withdrawn in U.S. Patent No. 6,342,221 ("the '221 patent"; Attorney Docket No. 3999.002584), one of the patents incorporated into the present specification. Applicants respectfully refer to the appeal brief filed in the '221 patent, which

resulted in withdrawal of the rejection over the term substantially (which appeal brief can be made of record in the present application should the Office require).

B. Tables

Claims 9-11 are further rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in reciting tables from the specification (Action at page 3).

Claims are permitted to define an invention by reference to a drawing or table. *Ex parte Fressola*, 27 USPQ 2d 1608 (Fed. Cir. 1993). In addition, claims should not be required to be so detailed as to obscure, rather than to particularly point out and distinctly claim the invention. *In re Smythe and Shamos*, 178 USPQ 279, 286 (C.C.P.A. 1973). Accordingly, present claims 9-11 are definite in referring to Table 3 and/or Table 4 of the specification. Indeed, the Federal Circuit's predecessor court stated that incorporation by reference is permitted "where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." *Fressola*, 27 USPQ 2d at 1609.

Nonetheless, and without acquiescing with the present rejection in any way, Applicants have elected to revise each of claims 9-11 to replace the succinct reference to Table 3 and/or Table 4 with the pertinent text from such tables.

The rejections under 35 U.S.C. § 112, second paragraph are therefore overcome and should be withdrawn.

VI. Rejection of Claims 51, 52 and 96 Under 35 U.S.C. § 112, First Paragraph

Claims 51, 52 and 96 are next rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly fails to enable pharmaceutical compositions comprising an antibody that competes with 3G4 for binding to PS. Although Applicants respectfully traverse, the rejection is overcome.

The rejection is *prima facie* improper for various reasons. Nonetheless, Applicants note that the Action has set forth a particular criterion, in the form of competition data, which will overcome the rejection, and the requested data is now supplied.

A. The Rejection is Improper

Claims 1-19, 23, 93-95 and 97-99 are free from this ground of rejection, which is applied only to the pharmaceutical compositions of claims 51, 52 and 96. As the antibodies of claims 1-19, 23, 93-95 and 97-99 are enabled, and as those of ordinary skill in the art can readily mix an antibody with a pharmaceutically acceptable carrier, claims 51, 52 and 96 must also be enabled. There is nothing in the addition of a pharmaceutically acceptable carrier that would turn an otherwise enabled and useful antibody into an antibody lacking enabling support² (see also, specification at Section I, concerning specific and credible uses of the claimed antibody compositions).

According to established practice, the specification "*must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements". *In re Marzocchi & Horton*, 169 USPQ 367 (CCPA 1971), emphasis as in original. The Action does not present sufficient reason to doubt that the teaching of the specification enables the claims. In attempting to cast doubt on the specification, the Action at pages 3-4 first cites *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). However, in *Wands*, the Federal Circuit found sufficient enabling support for the claims at issue and overturned the Office's rejection.

²Note also, lack of enablement rejection of pharmaceutical composition claims in co-pending Application Serial No. 10/642,099 (Attorney Docket No. 3999.003088), which the Action holds not to be patentably distinct from the present claims.

Most importantly, the Action at pages 4-9 has overlooked the fact that pharmaceutical composition and treatment method claims using any antibody that binds to an aminophospholipid, including any antibody that binds to PS, are already enabled. For example, see allowed claims in Applicants' co-pending anti-viral applications (Serial Nos. 10/642,120, 10/642,060, 10/642,124 and 10/642,122), which have the same specification and priority date as the present case. Thus, although Applicants presently choose to pursue claims directed to antibodies that compete with 3G4, a currently preferred antibody, the entire class of antibodies that bind to PS is already enabled for pharmaceutical uses.

Turning to antibodies that compete with 3G4, the Action has also overlooked the important feature of the claimed invention. Whilst the Action emphasizes the treatment of patients³ with so-called "broadly claimed" antibodies or antigen-binding fragments (*e.g.*, Action at pages 4-7), the most important feature of the invention is that the claimed antibodies "effectively compete with 3G4" for antigen binding. The claims are therefore only narrowly directed to "3G4-like antibodies" (see specification throughout, *e.g.*, specification at pages 11-12).

Simply put, by defining competing antibodies, the claims, by their very nature, already define antibodies that bind, and consequently function, like the 3G4 antibody. As pharmaceutical compositions and treatment with 3G4 are admittedly enabled, and as all pending claims cover only 3G4-like antibodies, there can be no valid enablement concerns. Thus, in contrast to the Action's allegation that the specification does not teach antibodies that will "predictably function in a pharmaceutical composition" (Action at page 8), the whole point of

³None of the claims recite treatment, of either patients or animals.

"competing" antibodies is that they will predictably function in the same manner as the parent antibody with which they compete.

The Action's citation of certain references at pages 6-9 (Gura, *Science*, 278:1041-1042, 1997, "Gura"; Mellman, *The Scientist*, 20(1):47,1-10, "Mellman"; Jain, *Scientific American*, 271(1):58-65, 1994, "Jain"; Curti, *Crit. Rev. in Oncology/Hematology*, 14:29-39, 1993, "Curti") also fails to cast doubt on the enabling support in the specification for several reasons. First, such references fail to counteract the actual data in the specification using 3G4, 9D2, 3SB and annexin conjugates. Second, the references do not even approximate to casting doubt on antibodies that compete with a proven successful antibody. Third, all cited references are limited to alleged problems in cancer treatment, whereas the claimed pharmaceuticals have demonstrated *in vivo* activity against viruses (see also, Action at bottom of page 4).

Fourth, even in regard to cancer, the cited references are not relevant as they concern problems of access and killing of all tumor cells, whereas the present invention acts against the readily accessible tumor blood vessels. Fifth, again in regard to using the claimed compositions to treat cancer, the cited references are either mis-quoted, irrelevant or actually support Applicants' position.

For example, Gura teaches that cancer drug development is turning toward defining molecular targets (the present invention defines the molecular target, PS)⁴. The Action overlooks all the positive statements in Mellman, such as "the veritable renaissance in monoclonal antibodies"; "clinical evidence clearly supports the idea that we should be able to

⁴The Action mis-quotes Gura, which does not state that only 39 drugs "have actually been shown to be useful for chemotherapy", but rather that only 39 drugs developed from screening assays and used exclusively for chemotherapy are approved by the FDA. Note also, as of early 2006, there are 17 antibody therapeutics on the market already and 135 in development for treating cancer and related immunological conditions. This represents a \$10 billion market (predicted to rise to \$22 billion in 2008), which represents about 6% of the worldwide pharmaceutical market.

mobilize the immune system for meaningful, even dramatic therapeutic benefit"; "immunotherapies... are among the most widely used and accepted medical treatments"; "antibodies, immunotherapies in their own right, have already been developed against cancer"; and "there is strong justification for further development in this area".

Jain is cited for the position that tumors resist penetration by drugs. Applicants are perplexed that the Action has cited Jain - - as the present invention solves the drug delivery problems of Jain by using antibodies that bind to PS exposed on tumor blood vessels, such that delivery into the solid tumor is not needed. Similarly with Curti, cited as concerning the defense mechanisms of neoplastic cells, which defeat chemotherapy treatment strategies, the present invention solves the neoplastic cell problems of Curti by using antibodies that bind to and destroy the normal endothelial cells of the tumor blood vessels.

In summary, and in contrast to the Action at page 9, it can be more than reasonably predicted that a pharmaceutical composition comprising an antibody particularly selected to bind to antigen in the same manner as 3G4 will function in the same manner as 3G4.

B. Antibody Competition Data

The foregoing reasoning alone is more than sufficient to overcome the present rejection. Irrespective, the Action indicates that the rejection will be overcome by data showing that 3G4 competes with another antibody that has proven anti-tumor activity, without evident pathology (Action at pages 5-6). Whilst this improperly shifts the burden to the Applicants, the solicited competition data is nonetheless provided herewith in the form of the Declaration of Philip E. Thorpe under 37 C.F.R. §1.132.

Before turning to Dr. Thorpe's declaration, Applicants again stress that the reasoning of the Action is flawed. The specification already shows anti-tumor effects of the 3G4, 3SB and

9D2 antibodies⁵, without evident pathology (Action at pages 5-6). As 3SB does not compete with 3G4, and yet is safe and effective, rather than supporting an enablement rejection, this actually shows that the enabling support is far greater than Applicants choose to claim.

In any event, the enclosed Thorpe declaration demonstrates that the 3G4 antibody effectively competes with the 9D2 antibody for binding to PS (Thorpe Declaration at paragraphs 8-12, Exhibit B to Thorpe Declaration). As shown in Exhibit B, increasing amounts of 3G4 (both murine 3G4 and chimeric 3G4) progressively inhibit 9D2 binding to PS, therefore showing effective antibody competition for binding to PS. As the original specification shows anti-tumor effects of the 9D2 antibody, without evident pathology, the 3G4-9D2 competition data of the Thorpe declaration definitively overcome the rejection.

The rejection under 35 U.S.C. § 112, first paragraph is therefore overcome and should be withdrawn.

VII. Rejection of Claims 1, 93, 94 and 97 Under 35 U.S.C. § 102(b)

Claims 1, 93, 94 and 97 are further rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Maneta-Peyret *et al.*, *J. Immunol. Methods*, 108:123-127, 1988 ("Maneta-Peyret"). Although Applicants respectfully traverse, the rejection is overcome.

Applicants appreciate the indication that claims 2-19, 23, 51, 52, 95, 96, 98 and 99 are free from this ground of rejection (Action at page 10). Moreover, Applicants appreciate that no claims have been rejected under 35 U.S.C. § 103(a) as legally obvious over Maneta-Peyret or any other reference(s), either alone or in combination.

In light of these findings, and without acquiescing with the present rejection in any way, all claims have been placed in condition for allowance using the "monoclonal" antibody

⁵The specification also includes anti-tumor data, without evident pathology, using PS-binding, annexin conjugates.

language already found to be acceptable in allowed claim 98 and claim 12 (not subject to prior art rejection). Accordingly, claims 1, 93, 94, 96 and 97 have each been revised to include the term "monoclonal"⁶.

The rejection of claims 1, 93, 94 and 97 under 35 U.S.C. § 102(b) is therefore clearly overcome and should be withdrawn.

The rejection is also *prima facie* improper and overcome as applied to current claim 122 (reflects claim 1 prior to amendment), again based upon the reasoning in the Action itself. As noted in Action at page 10, claim 1 already recited a "purified" antibody that competes with 3G4. Maneta-Peyret concerns only "polyclonal" antibodies, *i.e.*, a heterogeneous mixture of innumerable different antibodies. Therefore, the polyclonal antibodies of Maneta-Peyret could not, as a scientific fact, be any purified antibody, let alone a purified antibody that competes with 3G4 for antigen binding.

Accordingly, any rejection of claim 122 under 35 U.S.C. § 102(b) is also overcome and should be withdrawn.

VIII. Rejection of Claims for Obviousness-Type Double Patenting

Six provisional rejections under the judicially created doctrine of obviousness-type double patenting are also set forth, as follows:

claims 1, 7, 9-17, 19, 51, 93, 94, 96 and 97 over claims 1-30 of Serial No. 10/642,124 (Attorney Docket No. 3999.002984);

claims 1, 7, 9-17, 19, 51, 93, 94, 96 and 97 over claims 1-32 of Serial No. 10/642,122 (Attorney Docket No. 3999.002985);

⁶Should the Office wish to enter § 102(b) or § 103(a) rejections against any of claims 1-19, 23, 51, 52 and/or 93-121, that would have to be made as part of a Non-Final Office Action, being a new ground of rejection not necessitated by Applicants' amendment.

claims 1, 7, 9-17, 19, 51, 93, 94, 96 and 97 over claims 1-28 of Serial No. 10/642,060 (Attorney Docket No. 4001.002982);

claims 1-6, 9-17, 19, 51, 93, 94, 96 and 97 over claims 1-31 of Serial No. 10/642,099 (Attorney Docket No. 3999.003088);

claims 1, 9-17, 19, 51, 93, 94, 96 and 97 over claims 1-23 of Serial No. 10/642,064 (Attorney Docket No. 4001.003086); and

claims 1, 93, 94, 96 and 97 over claim 5 of Serial No. 10/642,118 (Attorney Docket No. 4001.003085).

Applicants do not necessarily agree with the reasoning set forth. In particular, the Action's comments regarding generic claims, species and prior art appear to blend anticipation, obviousness, species and genus together, whereas these are separate issues. MPEP Chapter 800 at page 800-19, column 2. The Action also overlooks scientific differences in the claims. Note that in application Serial Nos. 10/642,124, 10/642,122 and 10/642,060, the claims are directed to anti-viral inventions, and in application Serial No. 10/642,099, the claims are directed to conjugates, whereas the present claims are all directed to naked (unconjugated) antibodies.

Nonetheless, and without acquiescing with the provisional rejections, but solely to progress the present application to issue as soon as possible, Applicants elect to overcome the rejections by filing the enclosed terminal disclaimer and fee.

The provisional rejections are therefore overcome and should be withdrawn.

IX. Conclusion

This is a complete response to the referenced Official Action. In conclusion, Applicants submit that, in light of the foregoing remarks and accompanying documents, the present application is in condition for allowance and such favorable action is respectfully requested.

Should Examiner Goddard have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

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